NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUMAIRA KHAN, **Plaintiff,** **v.** **KARL STORZ ENDOSCOPY-AMERICA, INC. et al.,** **Defendants.**	**Civil Action No. 15-7822 (JLL) (JAD)** **OPINION**

JOSEPH A. DICKSON, U.S.M.J.

This matter comes before the Court upon Sumaira Khan's ("Plaintiff") Motion for Leave to File an Amended Complaint pursuant to Federal Rule of Civil Procedure 15 (the "Motion to Amend"). (ECF No. 29). Pursuant to Federal Rule of Civil Procedure 78, no oral argument was heard on Plaintiff's application. Upon careful consideration of the parties' submissions, and for the reasons stated below, Plaintiff's Motion to Amend is **GRANTED.**

I. BACKGROUND

On October 30, 2015, Plaintiff brought suit against Defendants Karl Storz Endoscopy-America, Inc. ("Defendant KSE"), Karl Storz Endovision, Inc., Karl Storz GMBH & Co. KG, Howard H. Jones, M.D., Noah A. Goldman, M.D., the Valley Hospital, Inc., and several fictitious Defendants (collectively "Defendants") "for damages suffered as a direct and proximate result of the defective and unreasonably dangerous surgical instrument, the Rotocut Power Morcellator ['the Morcellator'], used during her laparoscopic myomectomy procedure for the treatment of

uterine fibroids." (Compl., ECF No. 1, ¶ 1). Plaintiff alleges that as a result of the use of the Morcellator, she suffered extensive injuries including metastasized stage four (4) cancer. (Id. ¶ 2).

Plaintiff alleges the following causes of action against the Defendants: Count One: medical malpractice against Defendants Howard H. Jones, M.D., Noah A. Goldman, M.D., and the Valley Hospital (collectively "the Valley Hospital Defendants"); Count Two: lack of informed consent against the Valley Hospital Defendants; Count Three: violation of the New Jersey Products Liability Act for a defective product against Defendants Karl Storz Endoscopy-America, Inc., Karl Storz Endovision, Inc., Karl Storz GMBH & Co. KG (collectively the "Karl Storz Defendants"); Count Four: violation of the New Jersey Products Liability Act for failure to warn against the Karl Storz Defendants; Count Five: violation of the New Jersey Products Liability Act for breach of express warranty against the Karl Storz Defendants; and Count Six: fraudulent misrepresentation and omission against the Karl Storz Defendants.

The Valley Hospital Defendants filed an Answer and Crossclaim against the Karl Storz Defendants on December 29, 2015. (ECF No. 14). Defendant KSEA filed a Motion to Dismiss Plaintiff's Complaint and the Valley Hospital Defendants' Crossclaims on January 25, 2016. (ECF No. 22). On February 22, 2016, Plaintiff filed a Motion to Amend the Complaint. (ECF 29). The Honorable Jose L. Linares, U.S.D.J., terminated Defendant KSEA's Motion to Dismiss as moot, without prejudice to the refiling thereof upon adjudication of the Motion to Amend. (ECF No. 30).

Plaintiff seeks to amend her Complaint in order to:

> [R]emove Count 5 (Breach of Express Warranty against the Karl Storz Defendants) and Count 6 (Fraudulent Misrepresentation and Omission against the Karl Storz Defendants), and further clarify the allegations as pertained to Count 3 (Products Liability Act—Defective Product against the Karl Storz Defendants) and Count 4 (Products Liability Act—Failure to Warn against the Karl Storz

> Defendants) in accordance with the New Jersey Products Liability Act.

(Pl. Br., ECF No. 29-1, at 1) (emphasis added). Plaintiff argues that pursuant to Federal Rule of Civil Procedure 15(a)(2), the Court should grant Plaintiff's Motion to Amend as it is neither futile, unduly delayed, nor is any party prejudiced by the amendment. (Id. at 1, 4). On March 7, 2016, Defendant KSEA filed a brief in opposition to Plaintiff's Motion to Amend, arguing that Plaintiff's proposed Amended Complaint "still fails to set forth a claim upon which relief can be granted pursuant to Fed. R. Civ. P. 12(b)(6), rendering it futile." (Def. Opp. Br., ECF No. 32, at 1).

II. LEGAL STANDARD

Federal Rule of Civil Procedure 15(a) governs requests for leave to amend, allowing a party to amend its pleadings after obtaining the Court's leave or the written consent of its adversary. Under this liberal rule, the Court must "freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2); see also Wright & Miller section 1484, at 676 ("Subdivision (a)(2) encourages the court to look favorably on requests to amend."). This lenient standard ensures that "a particular claim will be decided on the merits rather than on technicalities." Dole v. Arco Chem. Co., 921 F.2d 484, 487 (3d Cir. 1990) (internal citation omitted); see also Sabatino v. Union Township, No., 2013 WL 1622306, at *6 (D.N.J. April 15, 2013) (internal citations omitted) (discussing that "if the underlying facts relied upon by a party might be a proper subject of relief, that party should have the opportunity to test its claims on the merits.").

The decision to grant or deny leave to amend under Rule 15(a) is "committed to the sound discretion of the district court." Arab African Int'l Bank v. Epstein, 10 F.3d 168, 174 (3d Cir. 1993). While courts have broad discretion to decide motions to amend, they must "heed Rule 15(a)'s mandate that amendments are to be granted freely in the interests of justice." Voilas et al. v. General Motors Corp., et al, 173 F.R.D. 389, 396 (D.N.J. 1997) (internal citations and quotations

omitted). In the absence of unfair prejudice, futility of amendment, undue delay, bad faith, or dilatory motive, the court must grant a request for leave to amend. Grayson v. Mayview State Hosp., 292 F.3d 103, 108 (3d Cir. 2002); see also Arthur v. Maersk, Inc., 434 F.3d 196, 204 (3d Cir. 2006) (stating that generally, leave to amend should be granted "unless equitable considerations render it otherwise unjust.").

Here, Defendant KSEA challenges Plaintiff's proposed amendments on "futility" grounds. A proposed amendment "'is futile if the amended complaint would not survive a motion to dismiss.'" County of Hudson v. Janiszewski, 351 F. App'x 662, 666 (3d Cir. 2009) (quoting Alvin v. Suzuki, 227 F.3d 107, 121 (3d Cir.2000)); In re NAHC, Inc. Sec. Litig., 306 F.3d 1314, 1332 (3d Cir. 2002) ("An amendment would be futile when 'the complaint, as amended, would fail to state a claim upon which relief could be granted.'") (internal citation omitted). Therefore, "[t]he futility analysis on a motion to amend is essentially the same as a Rule 12(b)(6) motion." Marjam Supply Co. v. Firestone Bldg. Prods. Co., LLC, No. 11–7119 (WJM), 2014 U.S. Dist. LEXIS 46572, at *9–10 (D.N.J. Apr. 4, 2014). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id.

The Court notes that Defendants bear the burden of establishing that Plaintiff's proposed amendments are futile, and that, "given the liberal standard applied to the amendment of pleadings," that burden is a "heavy" one. Pharmaceutical Sales & Consulting Corp. v. J.W.S. Delavau Co., 106 F. Supp. 2d 761, 764 (D.N.J. 2000); accord Marjam, 2014 U.S. Dist. LEXIS

46572, at *10. "Therefore, '[i]f a proposed amendment is not clearly futile, then denial of leave to amend is improper.'" Schiano v. MBNA, 05–1771, 2013 U.S. Dist. LEXIS 81440, at *45 (D.N.J. Feb. 11, 2013) (internal citations omitted).

III. DISCUSSION

a. Alternative Design

The New Jersey Product Liability Act (the "Act") provides that:

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it . . . was designed in a defective manner.

N.J.S.A. § 2A:58C-2. In other words, "[a]s a threshold matter in a design defect case, plaintiff must show that the 'product was defective, that the defect existed when the product left the defendant's control, and that the defect caused injury to a reasonably foreseeable user.'" Donlon v. Gluck Grp., LLC, No. 09-5379 (JEI), 2011 WL 6020574, at *3 (D.N.J. Dec. 2, 2011) (quoting Feldman v. Lederle Labs., 97 N.J. 429, 449 (1984)).

The Act does, however, protect manufacturers and sellers from liability under the following circumstances:

> In any product liability action against a manufacturer or seller for harm allegedly caused by a product that was designed in a defective manner, the manufacturer or seller shall not be liable if:
>
> (1) At the time the product left the control of the manufacturer, there was not a practical and technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the product[.]

N.J.S.A. § 2a:58c-3a(1). As such, "[']Plaintiffs who assert that the product could have been designed more safely must prove under a risk-utility analysis the existence of an alternative design

that is both practical and feasible.'" Schraeder v. Demilec (USA) LLC, No. 12-6074 (FSH), 2013 WL 5770670, at *2 (D.N.J. Oct. 22, 2013) (quoting Lewis v. Am. Cyanamid Co., 155 N.J. 544, 570–71, (1998)).

Plaintiff's original Complaint alleges the following:

> The Morcellator was unsafe for its intended and/or reasonably foreseeable purposes and uses at the time it was distributed, sold or supplied by the Karl Storz Defendants because the known side effects and adverse consequences outweighed the benefits of the product. The Morcellator left the Karl Storz Defendants' hands in this defective condition and caused dissemination and/or upstaging of unsuspected malignant tissue to spread throughout Plaintiff's abdomen and the gravity of that damage outweighed the burden on Defendants to adopt an alternative design or method and the adverse effect of such alternative design or method on the utility of the device.

(Compl., ECF No. 1, ¶ 122). Although Plaintiff's original Complaint references the surgical tissue bag elsewhere in the Complaint, (see Compl., ECF No. 1, ¶ 80d) ("[t]he Surgical Tissue Bag patent was publically available and was available to the Defendants, and/or known to Defendants, before they first sought approval of the Morcellator and before Plaintiff's surgery"), it does not specifically state that the surgical tissue bag is the alternative design. (See generally Compl., ECF No. 1).

Plaintiff's proposed Amended Complaint, however, states the following:

> 140. An available alternative design at the time the Morcellator left the hands of Karl Storz Defendants included the use of the surgical tissue bag, which was available since as early as 1991.
>
> 141. Defendants knew that use of the tissue bag could prevent the spread of malignant cells to healthy tissue in the body cavity, yet failed to require concomitant use of the bag, or warn that failure to use the tissue bag may result in the dissemination of cancerous cells throughout the body.
>
> 142. The defectively designed condition of the Morcellator rendered the product unreasonably dangerous and defective for its intended

> and reasonably foreseeable uses and was the producing and proximate cause of the injuries and damages sustained by Plaintiff, for which the Karl Storz Defendants are liable to Plaintiff.

(Prop. Am. Compl., ECF No. 29-2, ¶¶ 140-142).

Defendant KSEA argues that while "Plaintiff's claims against KSEA are now limited to design defect and failure to warn under the New Jersey Product Liability Act, N.J.S.A. § 2A:58C-1 *et. seq.*", "the Act bars Plaintiff's claim for design defect since Plaintiff still fails to identify a defect in the morcellator itself or a reasonable alternative design." (Def. Opp. Br., ECF No. 32, at 1) (emphasis removed). Defendant KSEA notes that although "Plaintiff alleges that the subject morcellator was defective in that it did not include a 'surgical tissue bag'", "Plaintiff's own allegations make clear that the surgical tissue bag is a medical device separate and apart from the morcellator which KSEA advised surgeons to use." (Id. at 6) (emphasis removed). Moreover, Defendant KSEA maintains that "Plaintiff's argument that the morcellator was defective because it lacked a tissue bag is not viable as its end result would necessarily obligate the morcellator to have been designed with other separate, discrete products. Such an alleged defect is not contemplated under the Act." (Id.).

Plaintiff replied arguing that she has "identified an alternative, practical design that would not have spread cancerous tissue" and Defendant "KSEA is wrong to contend otherwise". (Pl. Rep. Br., ECF No. 33, at 3). Plaintiff explained that this cause of action is premised on the argument that "the morcellator should have been designed with what is known as a 'surgical tissue bag,' which is a bag that prevents the shredded tissue from being sprayed and seeded throughout the abdomen and pelvis." (Id. at 4). Plaintiff argues that Defendant KSEA's argument that the surgical tissue bag is not a part of morcellator is simply incorrect because "[e]ssentially all products consist of multiple components (some of which prevent harm)." (Id. at 5).

This Court finds that the question of whether the surgical tissue bag is "an entirely separate, discrete product from the morcellator", (Def. Opp. Br., ECF No. 32, at 7), is a question of fact and/or for experts. Defendant KSEA argues that the addition of a separate product cannot be an alternative design; that the two are essentially mutually exclusive. Defendant KSEA does not, however, provide this Court with any case law to support that contention. Whether an appropriate alternative design to the morcellator includes a surgical tissue bag is an issue that should be litigated. This argument is one that should be decided after a full explication of facts and competing experts. Plaintiff's proposed Amended Complaint sufficiently pleads a cause of action under the Federal Rules of Civil Procedure for defective design and is, therefore, not futile.

b. Failure to Warn

Under the Act, a manufacturer or seller "[i]n any product liability action . . . shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction." N.J.S.A. § 2A:58C-4. The Act specifically sets forth what is considered an adequate warning:

> An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician. If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et

> seq., a rebuttable presumption shall arise that the warning or instruction is adequate.

Id. In order to overcome this presumption under New Jersey Law, "a plaintiff asserting a failure to warn claim based on an inadequate label or instructions has stricter pleading requirements. A plaintiff must plead specific facts alleging deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, or manipulation of the post-market regulatory process". Cornett v. Johnson & Johnson, 211 N.J. 362, 388 (2012) (internal citations and quotations omitted).

Defendant KSEA argues that "the Act bars Plaintiff's remaining claims for failure to warn and punitive damages as Plaintiff still fails to make the requisite allegations necessary to overcome the presumption of adequacy afforded to medical devices cleared by the United States Food and Drug Administration ('FDA')." (Def. Opp. Br., ECF No. 32, at 1). Plaintiff replied arguing that the rebuttable presumption is of "no help" to Defendant KSEA. (Pl. Rep. Br., ECF No. 33, at 6). "First, it is a rebuttable presumption that cannot help a defendant (like KSEA) who conceals information from the FDA. Second, KSEA's label was never approved by the FDA at all." (Id.).

Plaintiff's proposed Amended Complaint states the following:

> 69. In its 510(k) application, Karl Storz deliberately concealed peer-reviewed medical literature, safety information, and adverse events of the risk of spreading unsuspected cancerous tissue beyond the uterus when laparoscopic power morcellators are used during gynecologic surgeries intended to treat benign fibroids.
>
> 72. . . . Karl Storz remained silent and deliberately concealed and withheld the information that its power morcellators were causing harmful effects to women across the country, including Ms. Khan. Defendant was well aware of the risk of spreading unsuspected cancer prior to Ms. Khan's surgery in November 2013.
>
> 73. Pursuant to the mandatory Medical Device Reporting ("MDR") regulation, 21 C.F.R. 803.1, medical device manufacturers, such as Karl Stroz, are *required* to report to the FDA when they learn that

> any of their devices may have caused or contributed to death or serious injury.
>
> 74. Karl Storz did not comply with this mandatory reporting outlined in the MDR regulation, 21 C.F.R. 803. As such, the Karl Storz defendants knowingly withheld and misrepresented material, relevant information required to be submitted under the FDA's regulations. Thus, Plaintiff is entitled to punitive damages under N.J.S.A. 2A:58C-5.

(Prop. Am. Compl., ECF No. 29-2, ¶¶ 69, 72-74) (emphasis in original). Plaintiff further alleges:

> 149. As evidenced by the sheer volume of peer-reviewed medical literature, the numerous case reports and case series, and the FDA investigation as described above, Defendants deliberately concealed and did not disclose knowledge acquired after the Rotocut's 2006 510(k) clearance that the device was causing serious injuries and death.

(Prop. Am. Compl., ECF No. 29-2, ¶ 149).

Defendant KSEA argues that "Plaintiff must allege specific facts that KSEA deliberately concealed information from the FDA, failed to disclose after-acquired knowledge of harmful effects of its morcellator, and/or manipulated the post-market regulatory process to overcome the presumption of adequacy and set forth a *prima facie* claim." (Def. Opp. Br., ECF No. 32, at 11) (emphasis removed). This Court finds that Plaintiff's proposed Amended Complaint does just that. Notably, Defendant KSEA acknowledges that Paragraph 149 of Plaintiff's proposed Amended Complaint is the only one that "address[es] the requisite facts necessary to overcome the Act's presumption of adequacy". (Def. Opp. Br., ECF No. 32, at 11). Yet Defendant argues that "Plaintiff cannot overcome the statutory presumption of adequacy of the warnings. Accordingly, Plaintiff's failure to warn claim is barred by the Act and leave must be denied to Plaintiff to file the proposed First Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(6) as futile." (Id. at 14) (emphasis removed). This Court disagrees.

As stated above, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its fact.'" Iqbal, 556 U.S. at 678 (quoting Twombly, 550 U.S. 554). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. Therefore, Plaintiff only needs to provide enough factual content in the proposed Amended Complaint to allow this Court to draw the reasonable inference that Defendants KSEA "knowingly withheld or misrepresented information required to be submitted under the agency's regulations" in order to rebut the presumption of adequacy. This Court finds that Plaintiff has done so here and, therefore, Plaintiff's proposed amendment is not futile.

c. Punitive Damages

With regard to punitive damages, the Act states:

> Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq. and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations.

N.J.S.A. § 2A:58C-5c. There is, however, an exception, which provides:

> [W]here the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded. For purposes of this subsection, the terms "drug," "device," "food," and "food additive" have the meanings defined in the "Federal Food, Drug, and Cosmetic Act."

(Id.). Defendant argues that "Plaintiff's claims for punitive damages are [ ] barred as she cannot satisfy the statutory exception for such an award . . . [a]s . . . the proposed First Amended Complaint

is devoid of any specific facts that KSEA withheld or misrepresented information from/to the FDA regarding the subject morcellator." (Def. Opp. Br., ECF No. 32, at 16).

Plaintiff replied arguing that she "sufficiently pled specific facts that KSEA withheld or misrepresented information from the FDA." (Pl. Rep. Br., ECF No. 33, at 10) (citing Prop. Am. Compl., ECF No. 29-2, ¶¶ 69-74). This Court agrees. As explained above, this Court finds that Plaintiff has adequately pled facts that support Plaintiff's allegation that Defendant KSEA withheld or misrepresented information. Because Plaintiff's failure to warn claim has survived a Rule 12(b)(6) analysis, it follows that Plaintiff is entitled to seek punitive damages under the Act. The allegations Plaintiff advances are sufficient to satisfy the plausibility requirement under the Federal Rules of Civil Procedure. As such, Plaintiff's claim for punitive damages pass muster for pleading purposes.

IV. CONCLUSION

For the foregoing reasons, Plaintiff's Motion to Amend, (ECF No. 29), is **GRANTED.** An appropriate form of Order accompanies this Opinion.

8/11/16

JOSEPH A. DICKSON, U.S.M.J.

cc: Hon. Jose L. Linares, U.S.D.J.